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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/944,929
Filing Date: August 31, 2001
Appellant(s): BAKER ET AL.

C. Noel Kaman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 02 September 2005 appealing from the Office action mailed 06 October 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

10/677,471 – filed 02 October 2003

09/989,729 – filed 19 November 2001

09/993,748 – filed 14 November 2001

09/906,742 – filed 16 July 2001

09/904,011 – filed 11 July 2001

09/904,485 – filed 13 July 2001

The 10/677,471 application is directly related to the instant appeal because the claims are directed to the polypeptide PRO361, encoded by the polynucleotides claimed in the instant application. A related application, 10/735,014, filed December 12, 2003, which claims antibodies which bind to the PRO361 polypeptide, is currently being prosecuted. The other applications are related to the instant appeal because the central issue of the appeal is whether utility is demonstrated by activity in the MLR (mixed lymphocyte reaction) assay. Because the issue in question is the same, these appeals may be related to, directly affect or be directly affected by or have a bearing on the

Board's decision in the pending appeal. This list is not exhaustive, but are at least those appeals known to the Examiner in which the central issue of the appeal is whether utility is demonstrated by activity in the MLR (mixed lymphocyte reaction) assay.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is essentially correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

A substantially correct copy of appealed claims 25-41 appears on pages 31-34 of the Appendix to the appellant's brief. The minor errors are as follows: the status identifiers recited in claim 26 in incorrect since the claim is not currently amended.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

- Kahan, Current Opinion in Immunology. 4: 553-560, 1992.
- Piccotti et al., Transplantation, 67 (11): 1453-1460, 1999.
- Campo, et al., Biol. Trace Element Res., 79: 15-22, 2001 .
- Wolon et al., Cell Immunol. 149(2) : 402-408, 1993.
- Fung-Leung et al., Transplantation, 60(4) : 362-368, 1995.
- Townsend et al., Clin. Immunol. Immunopathol., 86(1) : 115-119, 1998
- Townsend et al., Blood, 88(8) :L 3038-3047, 1996.
- Furukawa et al., Clin. Immunol. Immunopathol. 79(1) : 25-35, 1996.
- Current Protocols in Immunology, unit 3.12, edited by J.E. Coligan, AM. Kruisbeek, D.H. Marglies, E.M. Shevach, W. Strober, National Institutes of Health, Published by John Wiley & Sons, Inc.
- Gubler et al., PNAS 88 : 4143-4147, 1991.
- Peterson et al., J. Clinical Oncology 21(12) : 2342-2348, 2003.
- Thurner et al., J. Experimental Medicine, 190(11) : 1669-1678, 1999.
- Basic and Clinical Immunology, Eighth Edition, edited by Stites et al., Appleton & Lange, Norwal. CT, 1994.
- Manual of Clinical Laboratory Immunology, Sixth Edition, edited by Rose et al., ASM Press, Washington, DC, 2002.
- US Patent No. 5,817,306 HASKILL et al. 10-1998 (newly cited by Examiner)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

The claims are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The claims are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, one skilled in the art clearly would not know how to use the claimed invention.

It was previously asserted by the Examiner that insufficient evidence was provided to support the position that the MLR assay was an art recognized *in vitro* assay that was predictive of general immune responses *in vivo*. Several references were cited during the prosecution of the instant application which demonstrated either a showing that the results of the MLR assay were consistent with *in vivo* activity or were inconsistent with *in vivo* activity. Upon review of the prior art, the Examiner found a patent that states "The mixed lymphocyte response (MLR) and phytohemagglutinin A (PHA) assays are valuable for identifying immune suppressive molecules *in vitro* that are useful for treating graft versus host disease. The results obtained from these assays are generally predictive of their *in vivo* effectiveness." (See column 12, lines 36-

41 of US Patent No. 5,817,306). Therefore, it is conceded that the MLR assay is art recognized for identifying molecules which suppress an immune response.

However, another basis for rejecting the claims for lack of utility has been the lack of support in the specification for the assertion that the polypeptide encoded by the DNA of the instant claims actually acts as an inhibitor of the proliferation of stimulated T-cells. In Example 34 on page 141, it is stated that "Any decreases [sic] below control is considered to be a positive result for an inhibitory compound, with decreases of less than or equal to 80% being preferred. However, any value less than control indicates an inhibitory effect for the test protein." (lines 33-35). The specification does not provide any values or data for the proteins tested in the assay. The specification does not provide any statistics for the values measured in the assay. The specification provides no information at all regarding the results of the assay except that a certain protein tested positive and the statement that "**any value less than control indicates an inhibitory effect for the test protein**".

If the claimed invention is to be used for therapeutic inhibition of the immune response of an individual, the question to ask is how are the results of the MLR assay related to the asserted utility of the claimed invention? The previous Office actions go into great depth regarding the nature of the MLR assay and host those skilled in the art use this assay and what kind of determinations can be made about compounds which are tested in this assay. The MLC (a.k.a. MLR) assay is a measure of alloreactivity of one individual to another individual. This reactivity is governed by the antigenic disparity between the two individuals which are being compared in the assay.

Depending on the individuals being tested, the MLC may indicate stimulation if they are HLA-disparate or the MLC may indicate no stimulation if the individuals are HLA-identical. The ability of the claimed invention to inhibit proliferation of T-cells may not be a general inhibition of lymphocyte proliferation, but rather a reaction to one of the MHC antigens on the responder cell. The instant specification fails to provide sufficient detail of the assay which was performed and fails to provide any data whatsoever in order for one of ordinary skill in the art to evaluate the conclusion that proliferation of stimulated T lymphocytes is inhibited by the polypeptide encoded by the claimed DNA. The art recognizes several controls as being essential for meaningful results for the MLC assay, including autologous controls, a control to determined maximum response, screening for possible HLA antibodies and growth support capability (Basic & Clinical Immunology, page 246). Furthermore, there is known inherent variability of individual cellular responses from day to day, which would clearly dictate the need for internal controls. The specification indicates that CD4-igG was used as a control, but it is not clear how this would control for background stimulation or provide for a measure of maximal stimulation. Lastly, the specification fails to provide any data or evidence of the results of the assay, therefore, one of ordinary skill in the art cannot evaluate the conclusion of the specification. The specification states that "[a]ny decreases [sic] below control is considered to be a positive result", however, this does not indicate that statistical significance must occur for determination of a positive result in the assay, and therefore, the polypeptide in question may not alter the proliferation of stimulated T-lymphocytes to a significant extent. In conclusion, the results of the MLC (a.k.a. MLR) assay as

disclosed in the specification for the polypeptide encoded by the claimed DNA do not support a specific and substantial utility for the claimed invention because one of ordinary skill in the art would not conclude that a molecule which tested positive in the assay of the specification wherein "any decreases [sic] below control is considered to be a positive result" would be useful as a molecule for therapeutically inhibiting an immune response in an individual (asserted use). There is insufficient data presented, as well as insufficient controls used, to conclude anything regarding the ability of the polypeptide encoded by the claimed DNA to be used in a substantial way to therapeutically inhibit the immune response of an individual, and further experimentation would be required to use the invention in this manner.

The claims are also rejected under 35 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, as set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(10) Response to Argument

Appellant argues, beginning at page 5 of the response, that the reference cited by the Examiner to show that there is no correlation between the ability to inhibit proliferation of lymphocytes in the MLR in vitro assay and that same ability in vivo, i.e Kahan et al., Piccotti et al., and Campo et al., are insufficient to make the prima facie case. However, as stated above, the disclosure of newly cited US Patent No. 5,817,306

establishes the state of the art at the time the invention was made that the results of the MLR assay are generally predictive of *in vivo* effects. Therefore, arguments directed to the correlation or predictive nature of the MLR assay are moot and will not be addressed further. However, arguments directed toward the disclosure of the specification and the conclusion that can be made from said disclosure will be addressed since they are critical to the holding of lack of utility for inhibition of T-lymphocyte proliferation by the claimed polypeptide.

Appellant states at page 5 of the response that the Declaration of Dr. Sherman Fong was submitted July 12, 2004. This declaration has been fully considered, but not found to be persuasive. Dr. Fong concludes "a PRO polypeptide shown to inhibit T-cell proliferation in the MLR assay where the activity is observed as 80% or less of the control, as specified in the present application, would be expected to find practical utility when an inhibition of the immune response is desired, such as in autoimmune diseases." (page 3, paragraph 10 of the Declaration). In assessing the weight to be given expert testimony, the Examiner may properly consider, among other things, the nature of the fact sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion. See Ex part Simpson, 61 USPQ2d 1009 (BPAI 2001), Cf. Redac Int'l. Ltd. V. Lotus Development Corp., 81 F.3d 1576, 38 USPQ2d 1665 (Fed. Cir. 1996), ParagonPodiatry Lab., Inc. v. KLM Lab., Inc., 948 F.2d 1182, 25 USPQ2d 1561, (Fed. Cir. 1993). In the instant situation, the nature of the fact sought to be established is whether or not the disclosure that the polypeptide, PRO361, encoded by

the claimed DNA, tested "positive" for inhibition in the MLR assay of Example 34, supports the assertion that it could be used to inhibit proliferation of stimulation T-lymphocytes and therefore, be used for therapeutic inhibition of the immune system. Dr. Fong's statement that "a polypeptide shown to inhibit T-cell proliferation in the MLR assay where the activity is observed as 80% or less of the control, as specified in the present application", does not specifically state that the polypeptide in question, i.e. PRO361, shows this degree (i.e. 80% or less) of inhibition compared to a control. The specification states at page 141 that values of 80% or less below the control value are "preferred", but that any value less than control is considered a positive result, and that the PRO 361 "tested positive". There is no disclosure, in the specification or in any other source, that the alleged decrease reported in the specification for the protein PRO361 was of any particular degree. The only conclusion that can be made from the evidence provided for the PRO 361 protein encoded by the claimed DNA is that the decrease was a value less than control since this was the standard provided for determination of a positive inhibition. The significance of this conclusion can be questioned since proper assay controls, deemed essential in the art, were not used and because the standard for determination of a positive response in the assay would not be accepted by those of skill in the art, since statistical significance is the standard for evaluating therapeutic value of a compound. The expert has interest in the outcome of the case since Dr. Fong is listed as an inventor and is employed by the assignee. Finally, the expert refers to Gubler et al. as factual support for the conclusion in the declaration. However, Gubler et al. is silent in regard to any activity possessed by the

protein encoded by the claimed DNA. Furthermore, Gubler do not appear to indicate that a protein shown to affect T-cell proliferation in a MLR with a particular level of activity would be expected to have the type of activity as that exhibited by known inhibitors or stimulators of T-cell proliferation in vivo. The Fong declaration evinces that the instant specification provides a mere invitation to experiment, and not a readily available utility. The PRO361 protein has not been shown to therapeutically inhibit the immune system. The specification merely demonstrates that the PRO361 protein inhibits stimulated T-cell proliferation below control It is not known whether this decrease is significant or what the relative decrease in proliferation is. In the absence of any of the above information, all that the specification does is present evidence that PRO361 protein may decrease T-cell proliferation and invites the artisan to determine the significance of this decrease and whether it is meaningful (i.e. useful for a therapeutic benefit). It remains that the specification is not sufficient to conclude anything about the nature of the activity of the PRO361 protein. Based on consideration of the evidence as a whole, the finding of lack of utility based on the MLR assay of Example 34 is proper.

Appellant argues at page 5-6 of the Brief that the standard for utility is that is "more likely than not" that the asserted utility is specific and substantial and that the three references cited by the Examiner do not suffice to make a prima facie case that it was more likely than not that no generalized correlation exists between the ability to inhibit proliferation of lymphocytes in the MLR assay and that same ability *in vivo* (page 6). As was stated above, the Examiner accepts in view of the patent cited (US Patent

No. 5,817,306, Haskell et al) that such a correlation exists, and therefore the arguments at pages 6 through the first paragraph of page 7 are moot. However, regarding appellants arguments concerning the Declaration of Dr. Sherman Fong and the controls used in the MLR assay (page 7, line 6 – page 8), it is maintained that the specification does not support the conclusion that the protein encoded by the claimed DNA inhibits proliferation of T-lymphocytes such that it would have therapeutic application for enhancing the immune response. As pointed out previously, no data is presented and the statement that proliferation was less than control is not sufficient for concluding that the protein would be useful for a therapeutic application, which is the asserted utility based on this assay. The assay relied upon in the instant specification is deficient in that proper art-recognized controls are not present, measured values of inhibition are not present, variability is not disclosed, statistical significance is not disclosed, such that an independent evaluation and conclusion cannot be made. While appellant argues that they have "provided sufficient information regarding how to characterize data gathered in the MLR assay" (page 8 of the response), the fact remains that there is not a specific and substantial utility set forth in the specification since a valid utility cannot be determined from the limited disclosure of the function of the protein in question as an inhibitor of T-cell proliferation. Citations by the appellant in the response regarding possible controls that could be utilized in the assay (pages 7-8) do not provide additional information regarding the actual information supplied in the specification regarding the results; rather, they could be utilized in further experimentation and determination of the utility of the disclosed protein and DNA

encoding said protein. One skilled in the art would have to carry out further research to determine whether or not the decrease in T-cell proliferation by PRO361 in the MLR is real and significant, and therefore support the use for therapeutic inhibition of immune response. Such further research requirements make it clear that the asserted utility is not yet in currently available form, i.e. it is no substantial. This further experimentation is part of the act of invention and until it has been undertaken, Appellant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[I]t is not a reward for the search, but compensation for its successful conclusion."

At pages 9-12, Appellant reviews case law pertaining to the legal standard for patentable utility, with which the Examiner does not take issue. At page 12, Appellant asserts that the phrase "immediate benefit to the public" does not necessarily have to mean the invention is currently available" to the public in order to satisfy utility requirements. "Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility." (MPEP §2170.01). The argument has been fully considered, but is not persuasive. MPEP §2170.01 also states

that when "further research is required to reasonably confirm the asserted utility, the claims do not meet the requirements of 35 USC 101." In the instant situation, further research would be required to reasonably confirm that the claimed protein inhibits T-cell proliferation to a degree that it would be useful therapeutically for inhibiting an immune response, which is the asserted utility in the specification.

Appellant states at page 12 of the Brief "Appellants have asserted that the claimed nucleic acid, which encodes the PRO361 polypeptide, is supported by a specific and substantial or a well-established utility based on the ability of the PRO361 polypeptide to inhibit proliferation of T-lymphocytes, as demonstrated in the MLR assay". Appellant's assertion is noted, but the facts of record and the disclosure of the specification do not support this conclusion. As pointed out previously, the specification indicates that "any decreases [sic] below control is considered to be a positive result", yet art recognized controls, which are considered to be necessary for determining a meaningful result, are not present. The specification fails to include any values which were obtained from the assay, so the results of the assay cannot be independently evaluated. If the degree of stimulation is less than the control, but within the variability of the assay, then one of ordinary skill in the art would not conclude that the protein tested is an inhibitor of T-cell proliferation, yet the specification would arrive at this conclusion. In order to be useful in the manner asserted in the specification (i.e. therapeutic enhancement of an immune response), the degree of stimulation of T-cell proliferation must be meaningful. One of ordinary skill in the art would usually evaluate this by observing a statistically significant decrease in T-cell proliferation below

baseline. However, based on the limited disclosure in the instant specification, no conclusions can be made as to the activity of the protein in his assay because proper controls are not provided and there is no data presented to evaluate. Therefore, further research would be required to reasonably confirm the asserted utility based on the MLR assay of Example 34.

Appellant's statement and arguments (pages 12-14) directed to use of the MLR to evaluate compounds for use as immunomodulators is noted. However, in view of the Examiner's concession that the MLR is an art accepted assay for this purpose, these arguments are moot.

Appellant again refers to the Declaration of Dr. Fong at page 14 of the Brief. As stated previously, the Declaration has been fully considered but is not persuasive. Appellant asserts that the "the Examiner must make a prima facie case establishing that, even in view of the above discussion, it is more likely than not that one of ordinary skill in the art would doubt the truth of the Appellant's assertion of utility based on the inhibitory activity of PRO361b as demonstrated in the MLR assay". However, it is maintained that based on the lack of sufficient data and proper controls, one of ordinary skill in the art would indeed conclude that a practical utility had been established.

Appellants argue at pages 16-19 that the references cited by the Examiner, i.e. Kahan et al., Piccotti et al., an Campo et al., do not support the argument that the *in vitro* results from a MLR assay are not necessarily correlated to *in vivo* effects. However, as stated above, the Examiner has conceded that the MLR assay is an art accepted assay

for evaluation of compounds as immunomodulators, and therefore, these arguments are moot.

At page 19-20, regarding the "second argument" of the examiner, i.e. that the disclosure fails to teach a substantial and specific utility since it does not disclose whether the PRO361 had a significant inhibitory effect in the MLR assay, appellant states that sufficient controls for the MLR assay are both known in the art and taught in the specification, and therefore there is no prima facie case of lack of utility. However, it is maintained that in the absence of data which can be evaluated, and compared to controls, one of ordinary skill in the art cannot conclude from the disclosure that the PRO361 had a significant negative or inhibitory effect. Since the disclosure simply states that "any" decrease over the control is considered a positive result, one could not determine from this limited information the significance of the effect. Appellants argue at pages 23-24 that they describe the MLR assay, and the controls used therein at page 141 of the specification, wherein it is disclosed that "CD4-IgG may be used as a control in practicing the MLR assay in connection with the present invention" and additionally, "Appellants disclose that cell culture media can be used as a control". Appellants also argue that they have incorporated by reference the procedures described in *Current Protocols in Immunology,* unit 3.12 (page 23). Appellants then describe certain disclosures present in this reference text. However, it remains unclear whether any or all of these controls and procedures were followed in the MLR assay in which the PRO361 was tested, and more importantly, what the numerical values and statistical significance of the results were. Without such information, one cannot

evaluate the utility of the disclosed protein and the DNA encoded it. Appellants again argue at page 24 that the disclosure of the effect of PRO361 contained in the specification, which states that decreases less than or equal to 80% of control values are preferred, but "any values less that control indicates an inhibitory effect", and the PRO361 tested positive, is sufficient to indicate the utility of PRO361. However, for the reasons above, it is maintained this disclosure alone is insufficient to indicate substantial utility, and further research would be required to reasonably confirm that the claimed protein inhibits T-cell proliferation to a degree that it would be useful therapeutically for inhibiting an immune response, which is the asserted utility in the specification.

Appellant again refers to the Declaration of Dr. Fong at page 24 and its opinion that a PRO polypeptide shown to inhibit T-cell proliferation in the MLR assay where the activity is observed as 80% or less of the control, one of skill in the art would expect to find a practical utility when an inhibition of the immune response is desired such as in autoimmune diseases", and that the Examiner must consider all of the evidence of record anew in considering affidavit evidence. However, as discussed above, in assessing the weight to be given expert testimony, the Examiner may properly consider, among other things, (1) the nature of the fact sought to be established (2) the strength of any opposing evidence, (3) the interest of the expert in the outcome of the case, and (4) the presence or absence of factual support for the expert's opinion. (1) In the instant case, the nature of the fact sought to be established is whether or not Example 34 of the specification demonstrates that the claimed invention, the DNA encoding PRO361,

would be useful for therapeutic inhibition of an immune response. (2) The art provides support that the results of the MLR assay are generally predictive of *in vivo* effects (Haskill et al.), but the art also teaches that proper controls are required from meaningful results. These controls appear to be lacking in the instant application. Additionally, the standard used in the specification (negative decreases below control are considered a "positive" result) would not be accepted by those in the art as indicating that the claimed invention would have therapeutic value for inhibiting an immune response. The art to which the invention pertains is immunology and the art accepted standard for determining biological activity is statistical significance. Since no values are provided, statistical significance cannot be ascertained. (3) Dr. Fong has an interest in the case since he is employed by the assignee. Finally, (4) while Dr. Fong bases his findings with reference to facts, the conclusions arrived at are not supported by those facts. For example, there is no evidence that the protein encoded by the claimed DNA, PRO361, inhibits the stimulation of T-cells to a level of at least 80% of control, the value noted by Fong to indicate inhibition activity. Additionally, the references reviewed by Dr. Fong (Guber et al., Peterson et al. and Thurner et al.) are directed to IL-12, and not to the PRO361 of the instant application. None of the references indicate that an activity of at least 80% in an MLR is indicative of a protein having the type of activity as that exhibited by IL-12. IN fact, none of the references use the results of the MLR for IL-12 to make predictions about the biological activities of any other compounds. The asserted correlation of an activity of at least 80% or less in an MLR with the biological activity of any molecule, including IL-12, is not supported by any

evidence of record, and appears to be the opinion of Dr. Fong. Based on the totality of the evidence, considering it anew, it is maintained that one skilled in the art would view the MLR assay of Example 34 as merely preliminary with regard to whether or not PRO361 would be useful for therapeutic inhibition of an immune response. Further research would have to be done in order to determine if PRO361 inhibits proliferation of T-lymphocytes and, if so, whether or not the inhibition is significant enough to reasonably confirm the usefulness of PRO361 protein for therapeutic inhibition of an immune response. Thus, the specification does not provide products or services in "currently available" form to the public, and the asserted utility is not substantial.

Appellant argues that at page 25 of the Brief that the claims are enabled for the same reasons as provided for utility, stating that the claimed DNA has a utility based on the utility of the PRO361 polypeptide. Appellants further set forth the Wands factors in support of arguments regarding the enablement issue. In their evaluation, Appellants again state that the MLR assay results disclosed in the specification are sufficient to provide guidance to one of skill in the art so that they would know how to use the instantly claimed DNA encoding the PRO361 polypeptide. However, for the reasons set forth above, it is maintained that the instantly claimed DNA encoding PRO361 does not have a specific and substantial utility, and therefore, one would implicitly not know how to use the invention. Accordingly, the arguments of the Appellants are not found convincing, and the rejection is maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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